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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/714,781      | 11/17/2003  | Sheena May Loosmore  | 454313-3161.5       | 2429             |

20999 7590 05/15/2007  
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| EXAMINER |
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SALVOZA, M FRANCO G

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1648

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| MAIL DATE | DELIVERY MODE |
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05/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/714,781

Applicant(s)

LOOSMORE ET AL.

Examiner

M. Franco Salvoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Salvoza.

2. Claims 1-21 have been amended.
3. Claims 23-29 have been canceled.
4. Claims 1-22 are pending and under consideration.

### ***Double Patenting***

### **WITHDRAWN**

Claims 1-29 conflict with claims 1-29 of 10/679520; Claims 1-29 were rejected under 35 U.S.C. 101 as claiming the same invention of claims 1-29 of 10/679520.

Applicant contends that the present application related to a vaccine composition and a method of providing a protective immune response, and thus the double patenting rejection should be withdrawn. In the alternative the rejections should be held in abeyance until such time as allowable subject matter has been determined.

In light of applicant's amendment, the statutory provisional double patenting is withdrawn.

### ***Claim Rejections - 35 USC § 112***

### **WITHDRAWN**

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Claims 17-20, 22 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 18 recited vaccine composition but there was no antecedent basis in claim 1.

Claim 19 lacked antecedent basis for the adjuvant.

Claims 18 and 20 refer to the composition, but the cited claims are drawn to methods, not compositions.

In light of applicant's amendments, the rejections are withdrawn.

***Claim Rejections - 35 USC § 102***

**WITHDRAWN**

Claims 1, 7, 10-12, 16 were rejected under 35 U.S.C. 102(e) as being anticipated by Kinney et al. (WO 01/60847), Example 6.

Applicant contends that Kinney is not available as a reference since the date of Kinney is August 23, 2001, and the present application claims priority to April 6, 2001.

Applicant's argument is found persuasive and the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

**WITHDRAWN**

Claims 17, 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al. WO 01/60847.

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Applicant contends that Kinney is not available as a reference since the date of Kinney is August 23, 2001, and the present application claims priority to April 6, 2001.

Applicant's argument is found persuasive and the rejection is withdrawn.

***Claim Rejections - 35 USC § 102***

**WITHDRAWN**

Claims 1-3, 7, 16 were rejected under 35 U.S.C. 102(b) as being anticipated by Yamschikov et al.

Applicant contends that in light of the amendment to recite a vaccine, the rejection is obviated.

Applicant's argument is considered and found persuasive. The rejection is withdrawn.

***Double Patenting***

**MAINTAINED and NEW, necessitated by amendment**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-27 of copending application 10/676502.

Applicant contends that the present application related to a vaccine composition and a method of providing a protective immune response, and thus the double patenting rejection should be withdrawn. In the alternative the rejections should be held in abeyance until such time as allowable subject matter has been determined.

The rejection is maintained for reasons of record, as the amended claims recite an obvious embodiment of the claims reciting an immunogenic composition to one of ordinary skill in the art.

Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 10/679520. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions amended to recite vaccines in the instant claims constitute an obvious embodiment of the claims reciting an immunogenic composition to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**NEW, necessitated by amendment**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 19, 20, 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 lacks antecedent basis for reciting the immunogenic composition.

Claim 20 now lacks antecedent basis for reciting an immunogenic composition.

***Claim Objection***

**NEW**

Claim 10 is objected to because of the following informalities: It does not recite a SEQ ID NO. as recited in claims 11 and 12 reciting the same Accession Number. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

**MAINTAINED**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 16-22 were rejected under 102(e) as being anticipated by Chang et al. (US 2003/0022849), Examples 9-11.

Applicant contends that a date of invention to at least match the Chang et al. reference can be established.

Until such documentation is submitted, the rejection is maintained, as Chang et al. also teaches vaccine compositions and meet the amended limitations.

***Claim Rejections - 35 USC § 103***

**MAINTAINED**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (US 2003/0022849).

Applicant contends that a date of invention to at least match the Chang et al. reference can be established.

Until such documentation is submitted, the rejection is maintained, as Chang et al. also teaches vaccine compositions and meet the amended limitations.



Claims 1-13, 15-18, 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti et al. (5744141), Chang et al. (US 2003/0022849), and Paoletti et al. 5505941.

Claims 21, 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti et al. (5744141), Chang et al. (US 2003/0022849), and Paoletti et al. 5505941 and further in view of Ramshaw et al.

Claims 14, 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti et al. (5744141), Chang et al. (US 2003/0022849), and Paoletti et al. 5505941 and further in view of Audonnet et al. WO 99/44633.

Applicant contends that none of the references relied on in the Office Action provide teaching or suggestion of the present invention or motivation to combine; that neither Paoletti (a) nor (b) teach a vaccine composition to induce a protective immune response against WNV; neither Paoletti (a) nor (b) teach use of WNV coding sequences in a poxvirus, nor any teaching, suggestion or motivation to modify the references. Further, the additional references Ramshaw, Paoletti (c) and Audonnet do not correct the deficiencies.

Applicant's arguments are considered but found unpersuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the references contain sufficient teachings providing motivation and a reasonable expectation of success: Paoletti et al. (5744141) teaches recombinant poxvirus expressing flavivirus genes for immunizing and vaccines; Chang et al. teaches immunogenic nucleic acid compositions to induce immune response against West Nile; and Paoletti et al. (5505941) teach the added benefits of using avipoxvirus for immunizing mammals or avians. Ramshaw et al. teaches the prime/boost methods for DNA, poxvirus and protein immunization; Audonnet teaches the use of carbomer adjuvant with live recombinant virus vaccines. Further, Audonnet the present application recites inventor Sheena May Loosmore, thus the Audonnet reference is "by another."

Claims 1-11, 16-18, 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti in view of Goverdhan et al. and Ostlund et al. as evidenced by Paoletti et al.

Claims 1-12, 16-18, 22, were rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti with Goverdhan et al. and Ostlund et al and further in view of Stocks et al. and Chang et al.

Claims 1-11, 13, 14, 16-20, 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti with Goverdhan and Ostlund and further in view of Mumford.

Claims 1-11, 15-18, 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti with Goverdhan and Ostlund et al. in further view of Varga et al.

Claims 1-11, 16-18, 21, 21 were rejected under Paoletti with Goverdhan and Ostlund et al. in further view of Ruitengerg et al.

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Applicant further contends Paoletti (d) does not describe the vaccination of horses, rather relies on Ostlund for the motivation; thus one of skill in the art would have no motivation to extrapolate from pigs to horses; one would have no motivation to combine the JEV of Paoletti et al. with the WNV of Goverdhan since: the vaccine in Goverdhan used killed WNV, which is different from vector vaccine, and there would be no motivation to prepare a vector vaccine of WNV based on killed WNV results; further, the WNV in Goverdhan was less protective than the JEV vaccine, wherein the WNV only resulted in a reduction of the severity of the disease following challenge with JEV; thus, one of skill in the art would have no motivation to select WNV to utilize in the development of a vaccine. Finally, applicants contend that the claimed invention provides surprising and unexpected results that enjoy real world success, pointing to Example 32 wherein one dose efficacy of a canarypox vectored WNV vaccine against WNV was described, wherein only 1/9 vaccinated horses developed WNV viremia.

Applicant's arguments are considered but not found persuasive.

In regards to Paoletti (d), Paoletti (d) is not so limiting and does not merely teach vaccination of swine using NYVAC and JEV, but also vaccination of other mammals including mice, cats, dogs, and humans, thus, further, in light of teachings of Goverdhan and Ostlund (teaching immunization with JEV protects animals against WNV; the need to develop vaccine against WNV in horses, respectively), one of skill in the art would have been motivated and had a reasonable expectation to extrapolate to another mammal (horses).

Further, Goverdhan was cited merely for teaching that immunization with JEV protects animals against WNV, and one of ordinary skill in the art would have had a reasonable expectation for success for making a vaccine for WNV in light of the teachings of Paoletti, since

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WNV is closely related to JEV, and Ostlund provides the motivation to develop anti-WNV vaccine in horses.

Further in regards to unexpected results and Example 32, the results are noted, however, the examination focuses on the invention as recited in the claims and claim language.

The rejections are maintained for reasons of record.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
M. Franco Salvoza  
Patent Examiner



**BRUCE R. CAMPPELL, PH.D  
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